specific adulterant using appropriate confirmatory validity test(s).

(5) Substituted blind specimens must be certified for creatinine concentration and specific gravity to satisfy the criteria for a substituted specimen using confirmatory creatinine and specific gravity tests, respectively.

(d) You must ensure that each blind specimen is indistinguishable to the laboratory from a normal specimen.

(1) You must submit blind specimens to the laboratory using the same channels (*e.g.*, via a regular collection site) through which employees' specimens are sent to the laboratory.

(2) You must ensure that the collector uses a CCF, places fictional initials on the specimen bottle label/seal, indicates for the MRO on Copy 2 that the specimen is a blind specimen, and discards Copies 4 and 5 (employer and employee copies).

(3) You must ensure that all blind specimens include split specimens.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35971, June 25, 2008]

§ 40.105 What happens if the laboratory reports a result different from that expected for a blind specimen?

(a) If you are an employer, MRO, or C/TPA who submits a blind specimen, and if the result reported to the MRO is different from the result expected, you must investigate the discrepancy.

(b) If the unexpected result is a false negative, you must provide the laboratory with the expected results (obtained from the supplier of the blind specimen), and direct the laboratory to determine the reason for the discrepancy.

(c) If the unexpected result is a false positive, adulterated, or substituted result, you must provide the laboratory with the expected results (obtained from the supplier of the blind specimen), and direct the laboratory to determine the reason for the discrepancy. You must also notify ODAPC of the discrepancy by telephone (202–366–3784) or e-mail (addresses are listed on the ODAPC Web site, *http://www.dot.gov/ost/dapc*). ODAPC will notify HHS who will take appropriate action.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35971, June 25, 2008]

§ 40.107 Who may inspect laboratories?

As a laboratory, you must permit an inspection, with or without prior notice, by ODAPC, a DOT agency, or a DOT-regulated employer that contracts with the laboratory for drug testing under the DOT drug testing program, or the designee of such an employer.

§ 40.109 What documentation must the laboratory keep, and for how long?

(a) As a laboratory, you must retain all records pertaining to each employee urine specimen for a minimum of two years.

(b) As a laboratory, you must also keep for two years employer-specific data required in § 40.111.

(c) Within the two-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that you retain the records for an additional period of time (*e.g.*, for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the records at the end of the two-year period.

§ 40.111 When and how must a laboratory disclose statistical summaries and other information it maintains?

(a) As a laboratory, you must transmit an aggregate statistical summary, by employer, of the data listed in Appendix B to this part to the employer on a semi-annual basis.

(1) The summary must not reveal the identity of any employee.

(2) In order to avoid sending data from which it is likely that information about an employee's test result can be readily inferred, you must not send a summary if the employer has fewer than five aggregate tests results.

(3) The summary must be sent by January 20 of each year for July 1 through December 31 of the prior year.

(4) The summary must also be sent by July 20 of each year for January 1 through June 30 of the current year.

(b) When the employer requests a summary in response to an inspection, audit, or review by a DOT agency, you must provide it unless the employer had fewer than five aggregate test results. In that case, you must send the

employer a report indicating that not enough testing was conducted to warrant a summary. You may transmit the summary or report by hard copy, fax, or other electronic means.

(c) You must also release information to appropriate parties as provided in §§ 40.329 and 40.331.

(d) As a laboratory, you must transmit an aggregate statistical summary of the data listed in Appendix C to this part to DOT on a semi-annual basis. The summary must be sent by January 31 of each year for July 1 through December 31 of the prior year; it must be sent by July 31 of each year for January 1 through June 30 of the current year.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35971, June 25, 2008]

§ 40.113 Where is other information concerning laboratories found in this regulation?

You can find more information concerning laboratories in several sections of this part:

§ 40.3—Definition.
§ 40.13—Prohibition on making specimens available for other purposes.
§ 40.31—Conflicts of interest concerning collectors.
§ 40.47—Laboratory rejections of test for improper form.
§ 40.125—Conflicts of interest concerning MROs.
§ 40.175—Role of first laboratory in split specimen tests.
§ 40.177—Role of second laboratory in split specimen tests (drugs).
§ 40.179—Role of second laboratory in split specimen tests (adulterants).
§ 40.181—Role of second laboratory in split specimen tests (substitution).
§§ 40.183–40.185—Transmission of split specimen test results to MRO.
§§ 40.201–40.205—Role in correcting errors.
§ 40.329—Release of information to employees.
§ 40.331—Limits on release of information.
§ 40.355—Role with respect to other service agents.

Subpart G—Medical Review Officers and the Verification Process

§ 40.121 Who is qualified to act as an MRO?

To be qualified to act as an MRO in the DOT drug testing program, you must meet each of the requirements of this section:

(a) *Credentials.* You must be a licensed physician (Doctor of Medicine or Osteopathy). If you are a licensed physician in any U.S., Canadian, or Mexican jurisdiction and meet the other requirements of this section, you are authorized to perform MRO services with respect to all covered employees, wherever they are located. For example, if you are licensed as an M.D. in one state or province in the U.S., Canada, or Mexico, you are not limited to performing MRO functions in that state or province, and you may perform MRO functions for employees in other states or provinces without becoming licensed to practice medicine in the other jurisdictions.

(b) *Basic knowledge.* You must be knowledgeable in the following areas:

(1) You must be knowledgeable about and have clinical experience in controlled substances abuse disorders, including detailed knowledge of alternative medical explanations for laboratory confirmed drug test results.

(2) You must be knowledgeable about issues relating to adulterated and substituted specimens as well as the possible medical causes of specimens having an invalid result.

(3) You must be knowledgeable about this part, the DOT MRO Guidelines, and the DOT agency regulations applicable to the employers for whom you evaluate drug test results, and you must keep current on any changes to these materials. The DOT MRO Guidelines document is available from ODAPC (Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590, 202–366–3784, or on the ODAPC web site (*http://www.dot.gov/ost/dapc*)).

(c) *Qualification training.* You must receive qualification training meeting the requirements of this paragraph (c).

(1) Qualification training must provide instruction on the following subjects:

(i) Collection procedures for urine specimens;

(ii) Chain of custody, reporting, and recordkeeping;

(iii) Interpretation of drug and validity tests results;